**UNITED STATES DISTRICT COURT**
**DISTRICT OF MINNESOTA**

| | |
|---|---|
| In re Bair Hugger Forced Air Warming Products Liability Litigation | MDL No. 15-2666 (JNE/FLN) |
| This Document Relates to All Actions | **EXPERT REPORT OF MICHAEL W. BUCK** |

# I. SUMMARY OF QUALIFICATIONS & EXPERIENCE

## A. Education and Training

My education and training have been focused on biology. I received a Bachelor of Arts in Biology, with Concentrations in Physical Science, Chemistry, Economics, and Psychology from Minot State University in 1989. I nearly completed a Master's Degree in Public Health in Industrial Hygiene at the University of Minnesota (39 graduate credits completed).

I have two recent publications: *Chapter 5: Air Monitoring for Quality Evaluation in Healthcare*, APIC 2015 INFECTION PREVENTION MANUAL FOR CONSTRUCTION AND RENOVATION, and DISPLACEMENT VENTILATION AS A VIABLE AIR SOLUTION FOR HOSPITAL PATIENT ROOMS (2010). Since 2003, I have provided presentations at various conferences on issues relating to industrial hygiene in the healthcare setting.

I have the following current certifications: Asbestos Contractor Supervisor Training certified by the Minnesota Department of Health (MDH):; Recognition of Indoor Air Quality Issues from the Midwest Center for Occupational Health and Safety; Introduction to Food and Air-Borne Fungi certification from the Centraal bureau voor Schimmelcultures Institute of the Royal Academy of Arts and Sciences at the Univeristy of Ottawa; Applied Thermographer – Infrared Technology certification from Restoration Consultants; NIOSH 582 – Asbestos Air Analysis certification from Delta Environmental Consultants; Building Inspector Hazardous

Materials; Asbestos Abatement Site Supervisor. In the past I have been certified as an OSHA 501 Certified Trainer; an Asbestos Project Designer; a Lead Risk Assessor, and a Lead Inspector. A copy of my Curriculum Vitae is attached as Exhibit A.

**B. Experience**

For over 25 years, I have worked in the Department of Environmental Health and Safety at the University of Minnesota. For over seventeen years, I have been an Environmental Health and Safety Compliance Specialist in the Department of Environmental Health and Safety at the University of Minnesota. In this capacity I have been responsible for conducting indoor air quality investigations, and have coordinated remediation activities. I am responsible for coordinating sample collection from the University Hospital's anesthetic gas employee exposure program, I manage the Departments' Micro Lab (including sample tracking and analysis), and I repair and maintain the Department air quality sampling equipment. Part of my current duties include review of various construction plans and evaluation of IAQ concerns. In addition, I audit the Facilities Management Hazardous Material Program, and work with outside contractors on abatement projects. From 1991 – 2000, I was a Principal Safety Technician in the Department of Environmental Health and Safety at the University of Minnesota, where my principal responsibilities included conducting building hazard assessments, as well as identifying and supervising asbestos identification and abatement projects.

### C. Medical/Legal Work Experience

Over the past ten years, I have been retained as an expert consultant on issues relating to hospital certification of critical care environments, including the BMT (Bone Marrow Transplant), ICU (Intensive Care Unit), NICU (Neonatal Intensive Care Unit), and OR (Operating Room), ventilation systems, and air and surface sampling. In my capacity as a consultant I have provided training on HVAC mechanics, as well as water infiltration remediation measures to various building managers. I have also provided consulting on industrial hygiene issues to real estate property management companies. As a consultant, my time is billed at $200/hour, $3,000 per day for deposition testimony, and $6,000 per day for trial testimony. I have provided no testimony by way of deposition and/or trial over the past four years.

## II. QUESTION PRESENTED

I was retained to evaluate whether or not the Bair Hugger Forced Air Warming System generates and/or omits particles.

## III. METHODOLOGY & METHODS

### A. Methodology and Approach to Test for Potential Particles

Healthcare professionals and facilities care deeply about particles, as particles can transmit pathogens. Particles themselves can be extremely small. By way of example, Figure 1, below, shows the size of various pathogens, including

bacteria. As illustrated in Figure 1, the vast majority of bacteria range in size from .3 to 1.2 microns. To provide additional context, Figure 2 illustrates how "big" a micron is, by showing a grain of salt (60 µm), dust mite waste (20 µm), and staphylococcus aureus (0.9 µm), each placed upon a cross section of a human hair (which has a diameter of 100 µm) to show scale.

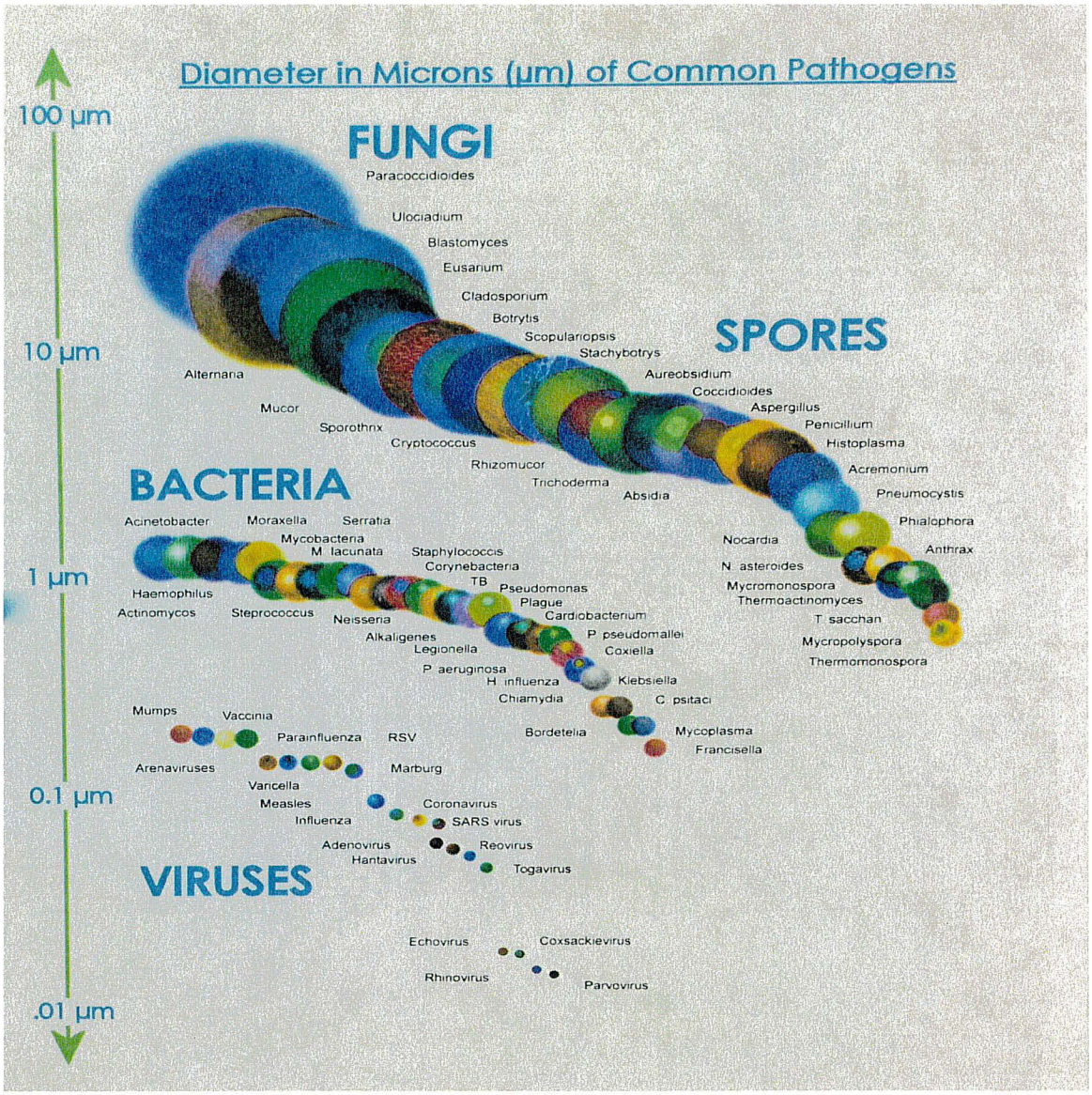



Figure 1

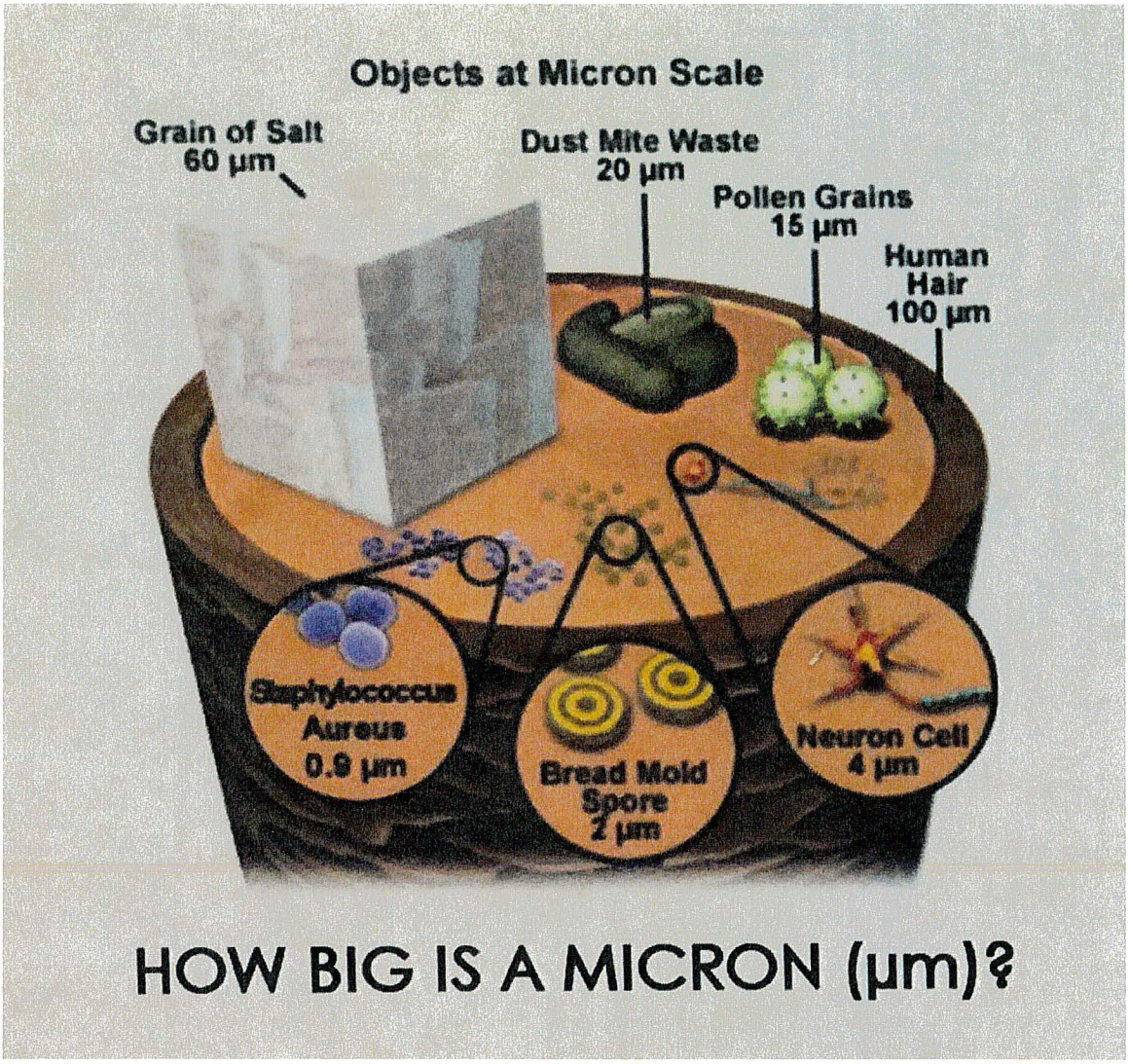



Figure 2

Because these particles are so small, specialized instrumentation is required to identify, measure and quantify them. The experiments discussed in this report were conducted in a cleanroom, using a particle counter.

A **cleanroom** or **clean room** is an environment, typically used in manufacturing, including of pharmaceutical products or scientific research. The cleanroom can be used to evaluate the source of particles. For example, a device such as a bubbling humidifier can be placed in the room and with manipulation of

airflow create an environment of droplet nuclei when saline is aerosolized. A comparison between particles generated by bubbling versus evaporation changed the way we deliver humidified air to patients. A filtered device that blows air can and should be evaluated in a clean room environment in the same manner to determine the difference – if any – with the applicable filter in place and with the applicable filter removed. This is considered an assessment of the *efficiency* of the filter.

A **particle counter** is a portable instrument that measures and reports air contamination. The particles can be differentiated into respective particle sizes using laser and optics to count sizes per unit volume of air. When the investigation includes air quality analysis, comparison data is useful to determine particle generation differences in mode of operation, location of filtration or difference in controls. For example what percentage reduction is observed from breathing zone particle sizes before and after using filtration for supplying air to a device. The experiments outlined below used a Fluke model 983 particle counter.

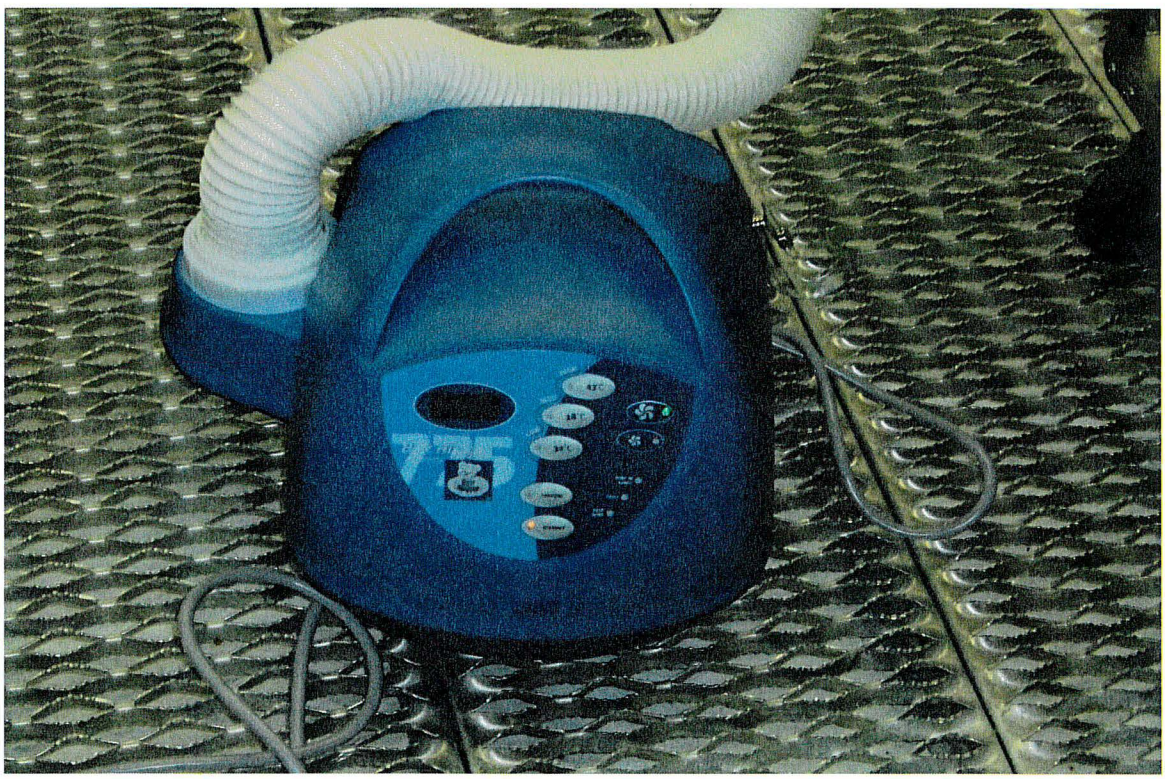
## B. Material and Methods for Testing Bair Hugger Devices

### *1. Tests on the Machines*

The Bair Hugger model units (1 used 750 series and 1 new 775 series) and its component parts (including the blower, filter, hose, and disposable blanket) were studied and evaluated to determine the number and size of any particles generated by the unit itself through normal operating procedures. This evaluation

was completed with a used Bair Hugger Model 750, and new Bair Hugger Model 775.[1] The filter efficiency was also evaluated by removing filter media and comparing and contrasting the number and size of particles recorded with the filter in-line versus when the filter was removed and the machine run without the filter in place.

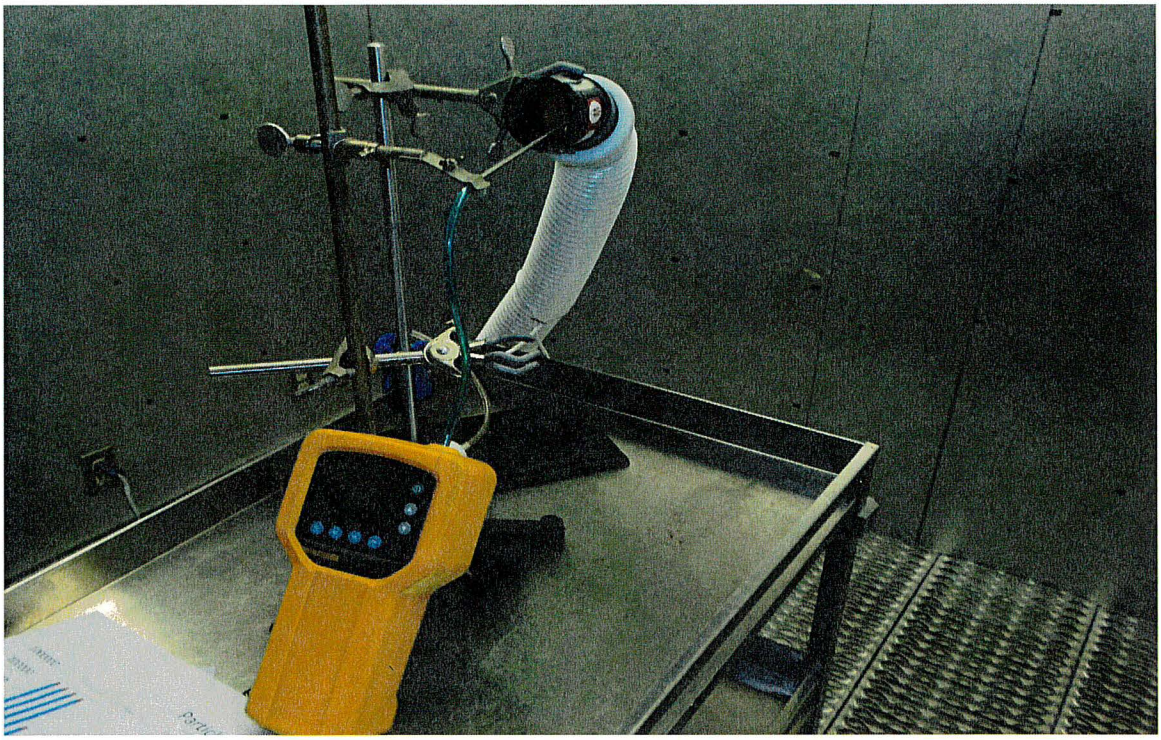
The first evaluation was carried out in a HEPA filtered (99.97% for .3µm sized particles) clean room using a laser optical particle counter that recorded differential particle sizes ranging from 0.3µ up to greater than 10µ in size. The particle counter isokinetic probe was mounted inside the Bair Hugger air supply hose with the Bair Hugger blower placed on the floor of the clean room.

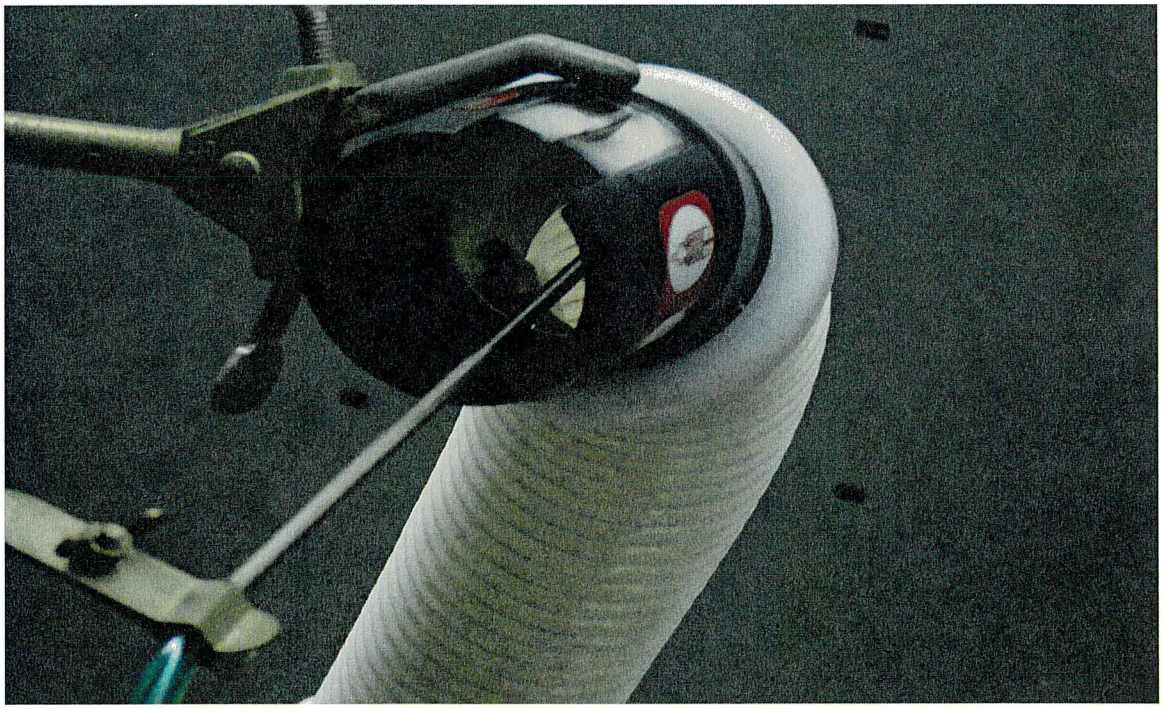


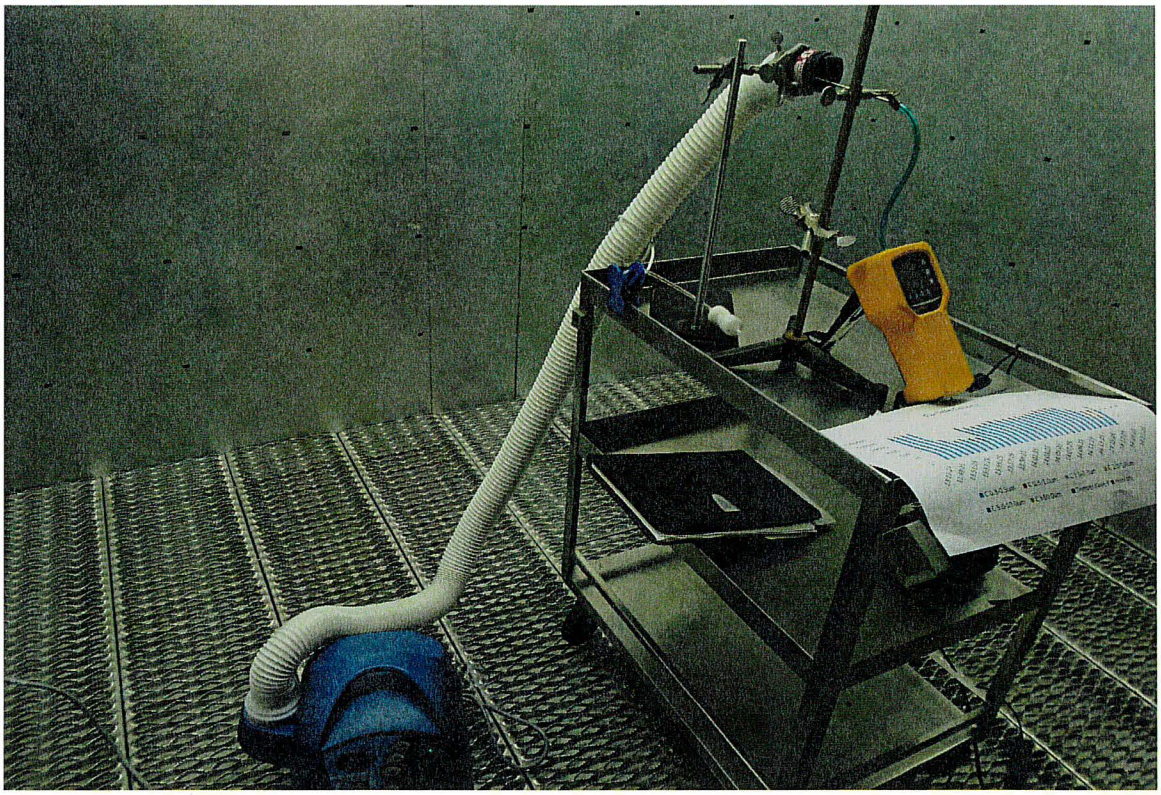
The Bair Hugger was evaluated using normal operating modes (ambient

[1] Both Bair Hugger devices were Model 750, provided by MDL Plaintiffs' Counsel.

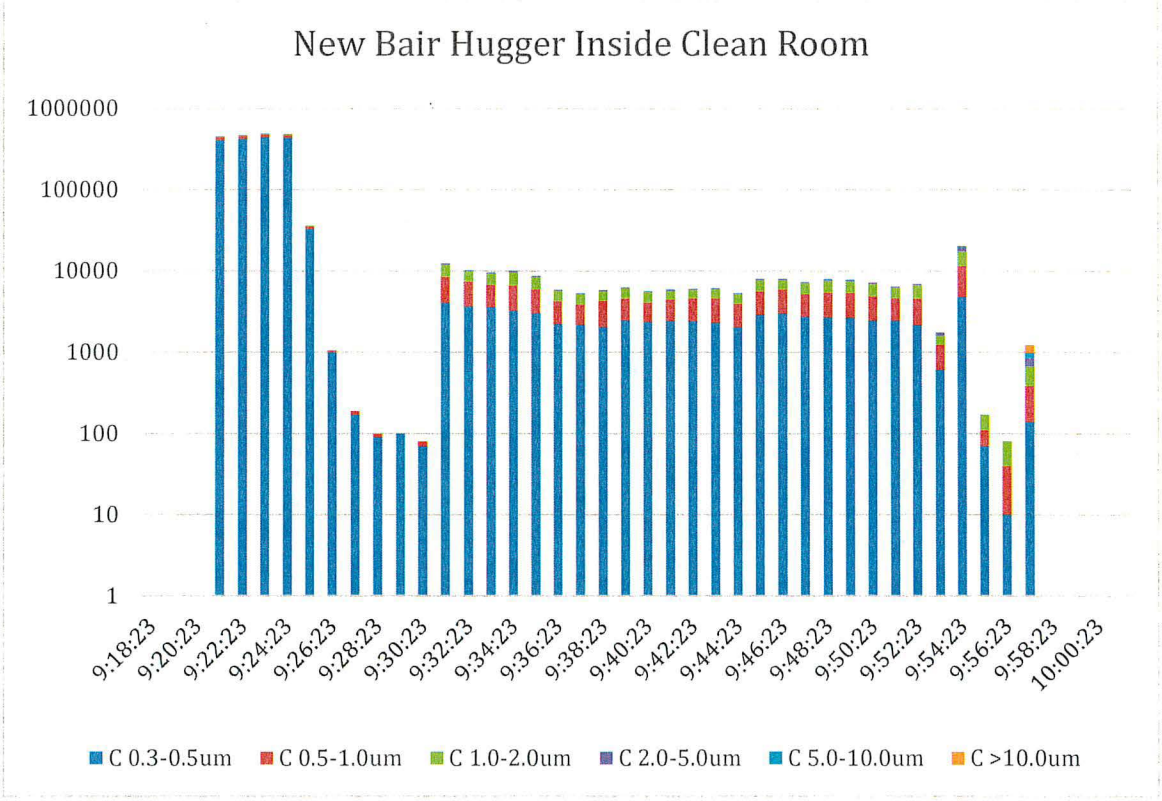
23°C, 38°C, 43°C, and blower unit on its side) to establish the initial discharge of air (particles) from the end of the air supply hose.





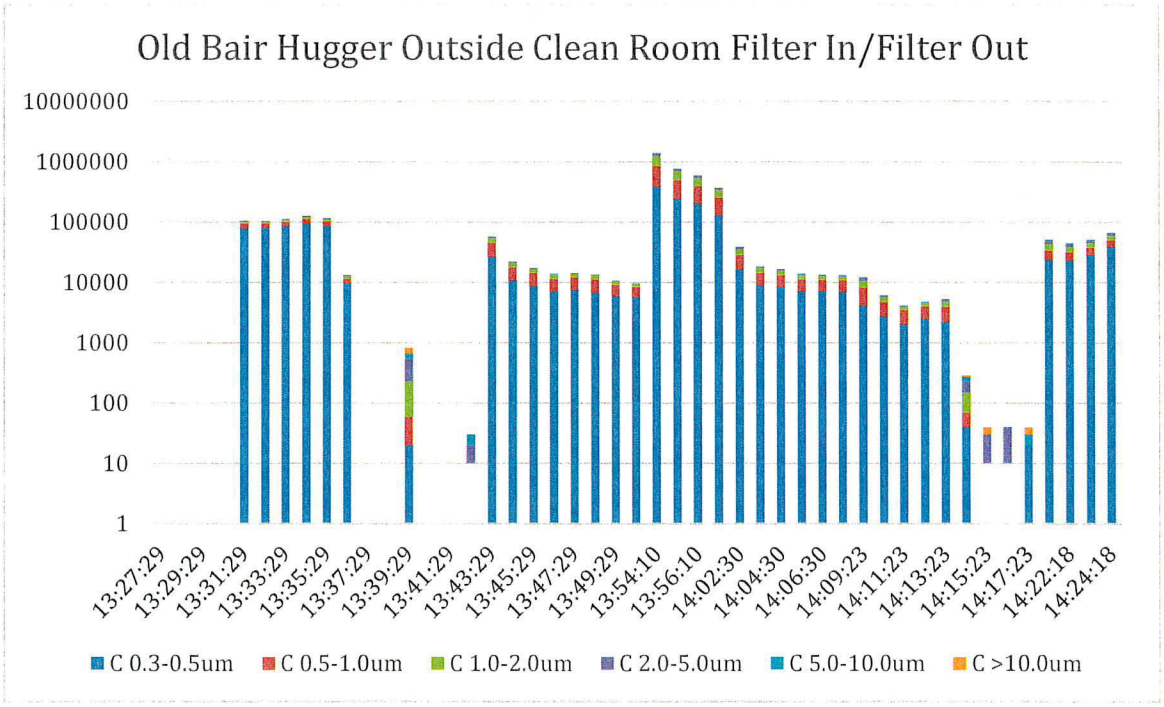


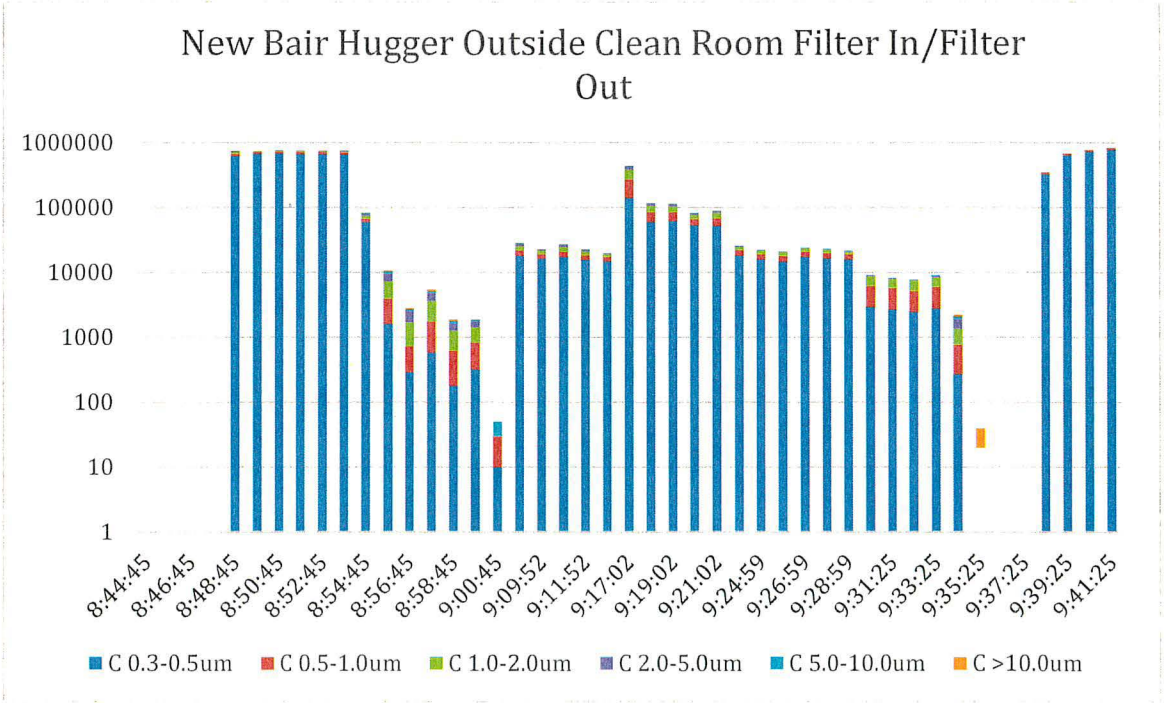
The evaluation of the air discharge was carried out through each operational mode and particle counts were collected at one minute intervals continuously through the end of the evaluation to validate air quality content of the Bair Hugger tested. This evaluation was completed with both a used Bair Hugger 750 and unused Bair Hugger model 775. These evaluations showed particles coming out of both the new and the used Bair Hugger devices.




A second evaluation was also carried out in a HEPA filtered (99.97% for .3µm sized particles) clean room using a particle counter that recorded differential particle sizes ranging from .3µ up to greater than 10µ in size. The particle counter isokinetic probe was mounted inside the Bair Hugger air supply hose which was placed inside the clean room to discharge. The Bair Hugger blower was placed outside the clean room on the floor. The Bair Hugger was evaluated using normal operating modes (ambient 23°C, 38°C, filter out, and filter in) to establish the initial discharge of air (particles) from the end of the air supply hose. The evaluation of the air discharge was carried out through each operational mode and particle counts were collected at one minute continuous intervals to validate air quality content and filter efficiency of the Bair Hugger tested. This evaluation was

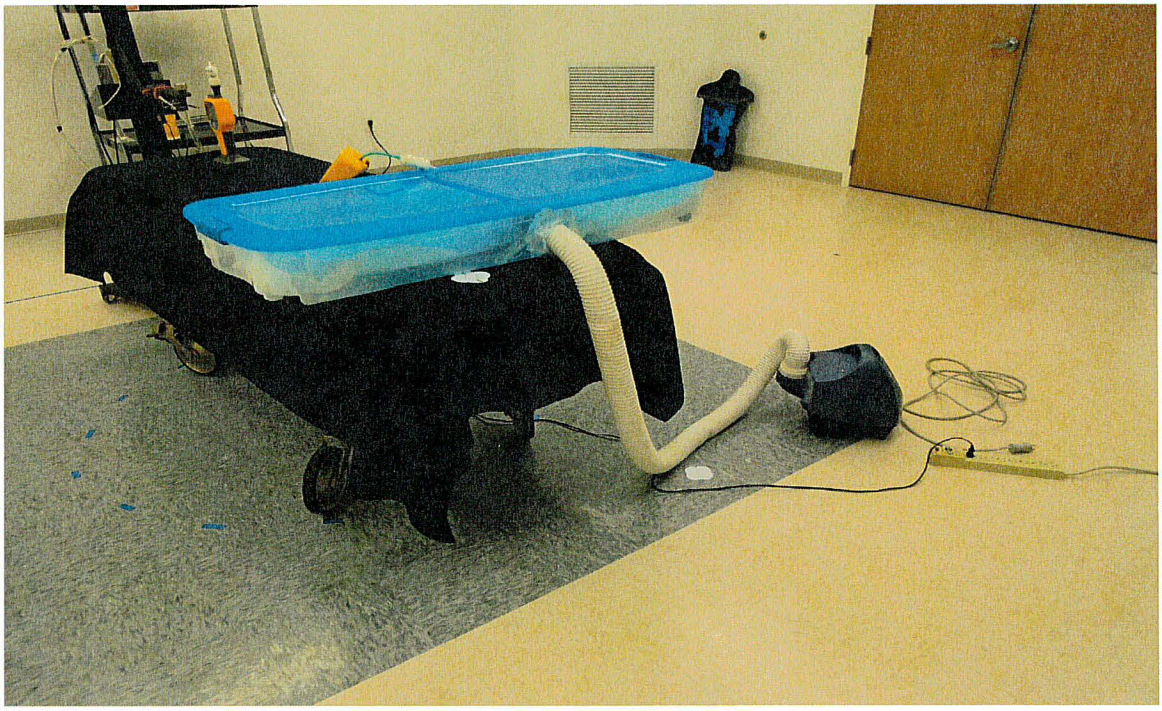
also completed with both a used Bair Hugger Model 750 and new Bair Hugger model 775. Again, these evaluations showed particles coming out of both the new and the used Bair Hugger devices.



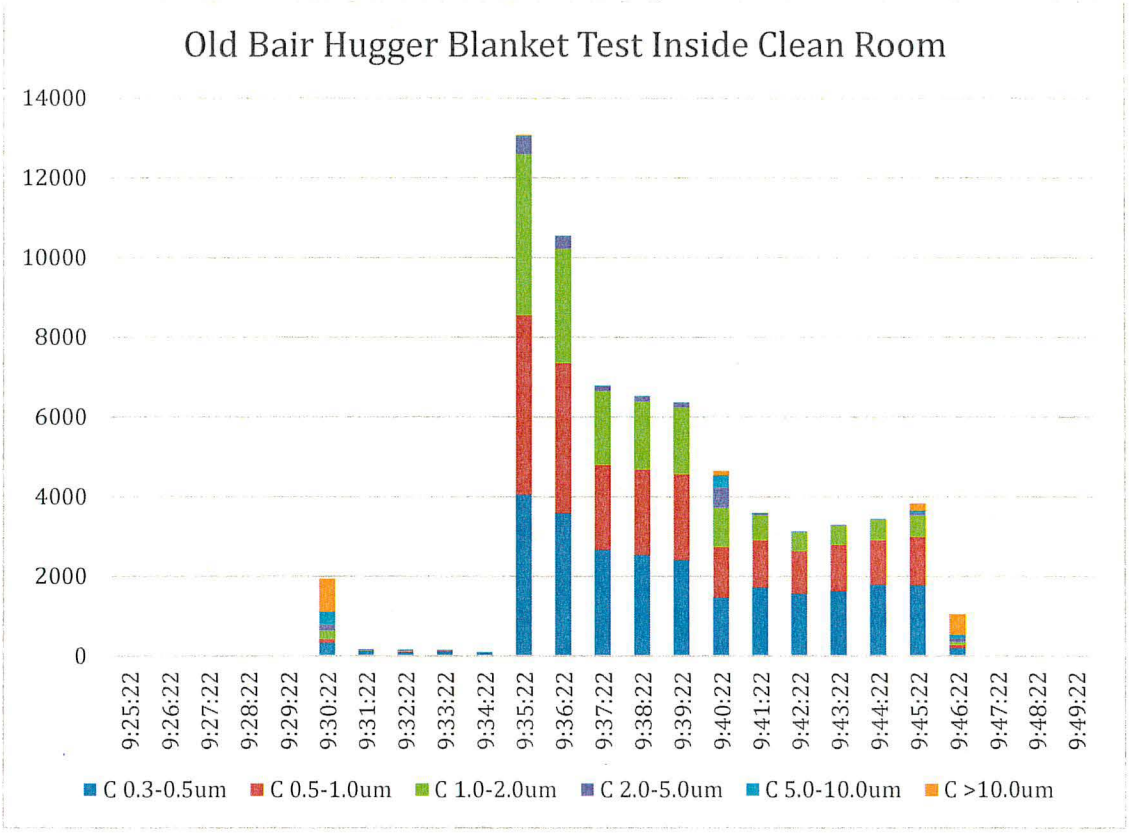
### *2. Tests on the Bair Hugger Machine with Blankets*

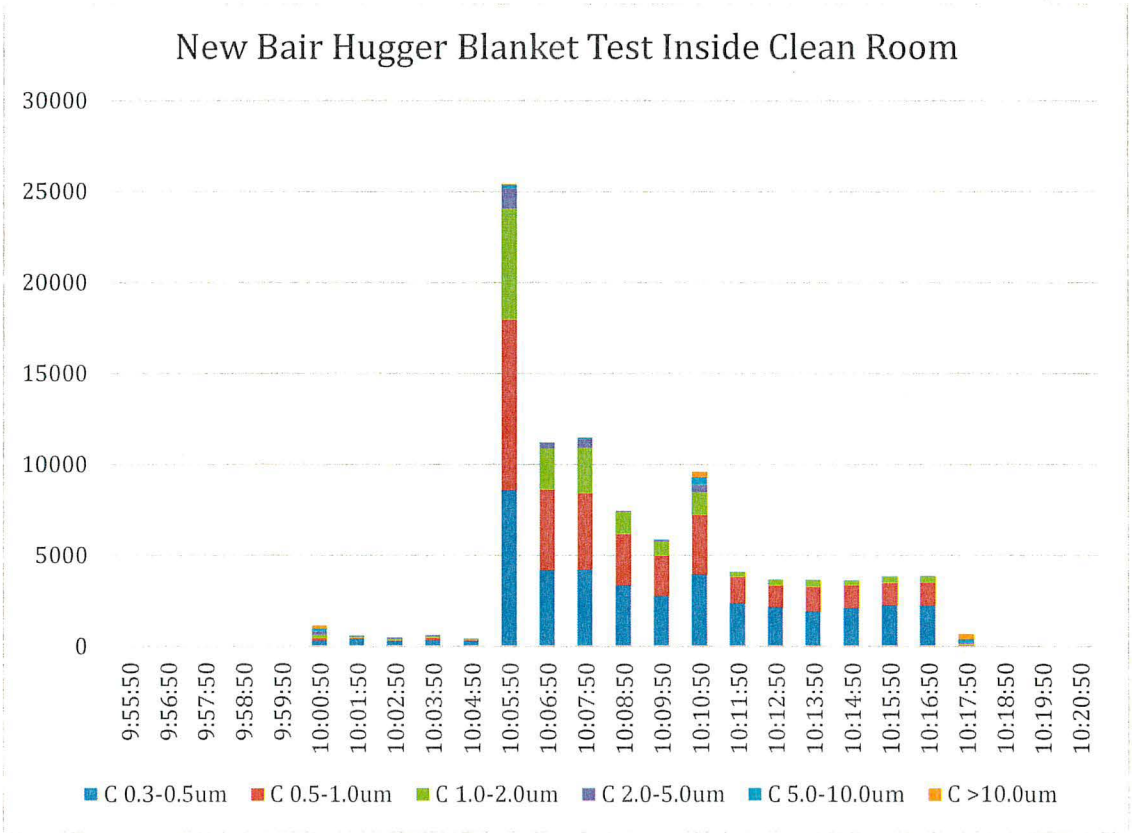
A third evaluation was carried out in a HEPA filtered (99.97% for .3µm sized particles) a simulated operating room using a laser optical particle counters that recorded differential particle sizes ranging from .02µ up to greater than 10µ in size. The particle counter isokinetic probe was mounted inside a container where the Bair Hugger air supply hose discharged with the Bair Hugger blower placed on the floor of the operating room.



The Bair Hugger was evaluated using normal operating modes (43°C, and blanket paper side down) to establish the initial discharge of air (particles) from the end of the air supply hose. In addition, a new upper body blanket (Model 52200) was attached to the air supply hose inside the box and particles that were released from the blanket were measured.

The evaluation of the air discharge was carried out through each operational mode and particle counts were collected at one minute continuous intervals to validate air quality content of the Bair Hugger and blanket. Again, this experiment confirmed particles coming out of both the new and used Bair Hugger machines when connected to new disposable upper body Bair Hugger blankets.

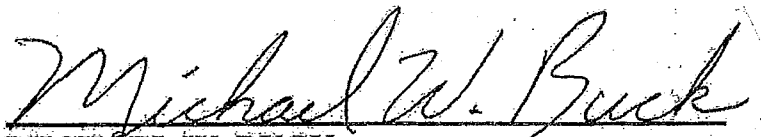

Old Bair Hugger Blanket Test Inside Clean Room
14000
12000
10000
8000
6000
4000
2000
0
9:25:22
9:26:22
9:27:22
9:28:22
9:29:22
9:30:22
9:31:22
9:32:22
9:33:22
9:34:22
9:35:22
9:36:22
9:37:22
9:38:22
9:39:22
9:40:22
9:41:22
9:42:22
9:43:22
9:44:22
9:45:22
9:46:22
9:47:22
9:48:22
9:49:22
C 0.3-0.5um
C 0.5-1.0um
C 1.0-2.0um
C 2.0-5.0um
C 5.0-10.0um
C >10.0um


New Bair Hugger Blanket Test Inside Clean Room
30000
25000
20000
15000
10000
5000
0
9:55:50
9:56:50
9:57:50
9:58:50
9:59:50
10:00:50
10:01:50
10:02:50
10:03:50
10:04:50
10:05:50
10:06:50
10:07:50
10:08:50
10:09:50
10:10:50
10:11:50
10:12:50
10:13:50
10:14:50
10:15:50
10:16:50
10:17:50
10:18:50
10:19:50
10:20:50
C 0.3-0.5um
C 0.5-1.0um
C 1.0-2.0um
C 2.0-5.0um
C 5.0-10.0um
C >10.0um

A complete copy of the log graphs reflecting data obtained from each of these evaluations is attached at Exhibit B.

## IV. CONCLUSIONS/SUMMARY OF OPINIONS

The evaluations showed clearly the Bair Huggers - through all operational modes - demonstrated increased production of particles from internal and/or external sources. This was true for both new and "used" machines, both with the filter in place and without the filter in place, as well as when connected to the disposable upper body blanket. These findings are consistent with both published literature and internal Arizant and 3M Company documents. It is my professional opinion that the Bair Hugger causes an increase in the number of particles in the operating room, and in particular, in close proximity to the surgical site. I reserve the right to amend the opinions in this report if further information becomes available to me.



**MICHAEL W. BUCK**
**HEALTH CARE AND ENVIRONMENTAL CONSULTING, INC.**
[redacted]